

**REMARKS**

Claims 1 and 4 have been amended. The amendment to claim 1 finds representative support in the specification at page 24, line 34 to page 25, line 2 and at page 29, lines 19-24. The amendment to claim 4 is formalistic in nature.

Applicants submit that no prohibited new matter has been introduced by the amendments.

**1. Rejection under 35 U.S.C. 112, first paragraph**

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, for the reasons detailed on pages 2-3 of the Office Action. More specifically, the Examiner asserts that the specification does not provide support for the tetrazolium compound and the sodium azide being present at the same time during the redox reaction.

While Applicants do not acquiesce to the merits of the Examiner's rejection, Applicants have, to expedite prosecution of the subject application, amended claim 1 to reflect the Examiner's acknowledgement that the specification does support "adding a tetrazolium compound and sodium azide to hemolyzed sample...." In view of this amendment, Applicants respectfully request that this rejection be withdrawn.

**2. Rejection under 35 U.S.C. 103(a)**

Claims 1, 2, 4-11 and 13-31 are rejected under 35 U.S.C. 103(a) as obvious over Komori in view of Yoshida and Ishimaru and further in view of Montellano, Kwan, Fry and Ledis as detailed on pages 3-11 of the Office Action.

Applicants submit that the claimed invention is distinguishable over the cited combination of references at least for the following reasons:

Komori clearly does not teach or suggest a pretreatment step to remove glycosylated amino acid contaminants with a FAOD (defined as a "degradation FAOD") to facilitate a more accurate measurement of a glycosylated protein as claimed by Applicants. The Examiner appears to assert that Komori does not teach that the order of adding the FAOD is limited and therefore, Komori somehow teaches Applicants' pretreatment step. Applicants respectfully disagree. The only pretreatment step disclosed or suggested in Komori involves the addition of a tetrazolium compound "so as to eliminate the influence of any reducing substance contained in the sample"

(paragraph [0010] of Komori). The FAOD is used in Komori only for the purpose of measuring the amount of an analyte in a sample, where the analyte may be a “glycated protein such as glycated hemoglobin and glycated albumin, glycated peptide, glycated amino acid, glucose, uric acid, cholesterol, creatinine, sarcosine, glycerol, and the like...” (paragraph [0029] of Komori). There is no contemplation in Komori of using the FAOD for any other purpose, such as for removing contaminants from a sample that interfere with the accuracy of the measurement of a desired analyte present in the sample, as claimed by Applicants. Even the Examiner acknowledges on page 7 of the Office Action that Komori does not teach a FAOD for degradation. Applicants submit that with no disclosure of a FAOD for degradation, Komori cannot be held out as teaching a pretreatment step in which glycated amino acids are degraded and removed from a sample before the amount of a glycated protein present in the sample is measured.

The Examiner appears to assert on page 8 of the Office Action that the teaching of Yoshida regarding FAOD's which are capable of performing similarly to Applicants' degradation FAOD, coupled with the disclosure at the 3rd paragraph of the second column of page 504 of Yoshida, somehow renders obvious Applicants' claimed pretreatment step involving a degradation FAOD. Applicants respectfully disagree. Simply because a material may be capable of performing a function, does not mean that it is obvious to use the material for this function in the absence of a rationale for doing so. The section of Yoshida cited by the Examiner (at page 504) relates to obtaining accurate measurements of glycated proteins in a sample by developing a particular FAOD that exhibits the highest selectivity for a particular glycated protein. In the example given, it is suggested that a FAOD that is highly selective for a glycated amino acid such as valine would be expected to also be highly selective towards a glycated protein whose N-terminal valine residue is also glycated. Nothing in this passage of Yoshida or any other section of Yoshida contemplates Applicants' pretreatment step of adding a degradation FAOD to a sample so that a glycated free amino acid that is present in the sample as a contaminant is degraded and removed from the sample by the degradation FAOD to allow a more accurate measurement of a glycated protein present in the sample. In fact, the closing sentence of Yoshida on page 505 states that “further studies...will be focused on engineering of the enzyme with characteristics more suitable for direct measurement of glycated proteins in blood serum....” This sentence can be viewed as teaching away from Applicants' approach to

the measurement of a glycated protein in a sample by first employing a pretreatment step with a degradation FAOD to remove glycated amino acids to improve the accuracy of the measurement.

Fry is held out by the Examiner on page 8 of the Office Action as teaching the formation of free amino acids that are glycated in parenteral nutritional solutions used for intravenous feeding. Applicants submit that Fry does not teach or suggest whether such glycated amino acids could inhibit or adversely affect the measurement of glycated proteins using FAOD. In fact, Fry does not teach any problems associated with the presence of glycated amino acids. Therefore, no rationale exists from a reading of Fry for attempting to degrade and remove glycated amino acids from a sample before measurement of the sample occurs.

None of the remaining cited secondary references, either alone or in combination, are able to remedy the above-discussed defects present in the primary reference of Komori and the secondary references of Yoshida and Fry. Accordingly, Applicants respectfully request that this rejection be withdrawn.

### **3. Conclusion**

The foregoing amendments and remarks are being made to place the application in condition for allowance. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

The Commissioner is hereby authorized by this paper to charge any additional fees which are required by this filing to Deposit Account No. 50-0310.

Respectfully Submitted,  
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